

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/674,914
Filing Date: September 30, 2003
Applicant: Bevil J. Hogg
Group Art Unit: 3736
Examiner: Huong Q. Nguyen
Title: Method and Apparatus for Improved Surgical Navigation
Employing Electronic Identification with Automatically
Actuated Flexible Medical Devices
Attorney Docket: 5236-000452

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**SUPPLEMENTAL APPEAL BRIEF
UNDER 37 C.F.R. § 41.37**

Sir:

The Notice of Appeal in this Application was mailed on June 26, 2008. Subsequent to the August 26, 2008 filing of an Appeal Brief, a Notice of Non-Compliant Appeal Brief was mailed September 11, 2008. This Supplemental Appeal Brief is submitted to reflect the required statement as to *each* ground of appeal. The fee required under 37 C.F.R. §1.17(f) was previously submitted with the Appeal Brief filed August 26, 2008.

APPELLANT'S BRIEF ON APPEAL

Pursuant to 37 C.F.R. § 41.37, Appellants submit their Brief on Appeal, as follows:

REAL PARTY IN INTEREST – UNDER 37 C.F.R. § 41.37(c)(1)(i)

The real party in interest in this appeal is Stereotaxis, Inc., a Delaware corporation, having a place of business at 4320 Forest Park Avenue, Suite 100, St. Louis, MO 63108, by virtue of an assignment recorded at Reel 014802, Frame 0204.

RELATED APPEALS & INTERFERENCES - UNDER 37 C.F.R. § 41.37(c)(1)(ii)

To the best of Appellants' knowledge, no other appeals or interferences are pending which will directly affect, be directly affected by or have a bearing on the Board's decision in the present pending appeal.

STATUS OF THE CLAIMS – UNDER 37 C.F.R. § 41.37(c)(1)(iii)

On June 26, 2008, Appellants appealed from the final rejection of Claims 1-6, 8-17, 38-40 and 52. Claims 7, 18-37, 41-51 and 53 have been cancelled without prejudice.

- A copy of the claims presently being appealed (i.e., Claims 1-6, 8-17, 38-40 and 52) is provided in the attached Claims Appendix.

- A copy of the Final Office Action mailed March 27, 2008 placing claims 1-6, 8-17, 38-40 and 52 of the present application under final rejection is provided in the attached Evidence appendix.

STATUS OF AMENDMENTS – UNDER 37 C.F.R. § 41.37(c)(1)(iv)

A Final Office Action was mailed March 27, 2008. Subsequently, an Amendment after Final was mailed May 13, 2008, which the Examiner has not responded to.

SUMMARY OF CLAIMED SUBJECT MATTER – UNDER 37 C.F.R. § 41.37(c)(1)(v)

Independent Claim 1

A medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body, the system comprising:

an elongate flexible medical device having on its distal end portion one or more magnetically responsive elements that respond to an externally applied magnetic field to change the direction of the distal end of the medical device, and an electronic identification device on the elongate medical device that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, and identification information that provides for elongate flexible medical device identification;

a navigation device configured to create a magnetic field used to steer the elongate flexible medical device, and to determine, as a function of the physical and geometric properties, actuation control variables for an applied actuation consisting essentially of an external magnetic field, where the navigation device determines and applies an appropriate magnetic field direction for actuating the distal end of an elongate flexible medical device and thereby changing its orientation;

an electronic interface for selectively operating the navigation device for selectively controlling the orientation of the distal end of the elongate flexible medical device, the electronic interface comprising a processor and at least one software program that enables navigation control only in the presence of the electronic identification device, wherein the interface provides actuation instructions to the navigation device for controlling the distal end of the device, which instructions take into account the physical and geometric properties of the elongate medical device, including the number of magnetically responsive elements and spacing therebetween, that were obtained from the electronic identification device at the same selected operating point spaced from the front face of the magnet.

With regard to independent claim 1, the present application states in ¶ [0022] that “the medical device 51 generally comprises a flexible and usually hollow shaft 97, a magnetically responsive element 101 that imparts device actuation in the distal portion” and “A device identification pod 121 incorporating stored electronic identification information is affixed to the device.” The “device identification stored in pod 121 discloses a set {p} of physical and geometrical properties...[which] include one or more of several quantities such as length of device segments, elastic property of device segments, stiffness, device cross sectional details, magnet dimensions, magnet type and other magnet characteristics, the number of magnets and their spacing.” (see ¶ [0030])

The Application discloses “a navigational control system 57” which is a “magnet system that creates a magnetic field that can be used to steer the device 51...[where] a magnetically responsive element on the distal end of the medical device responds to the external magnetic field to change the direction of the distal end of the device.” (see ¶ [0020]) With regard to the set of physical and geometrical properties, the Application states that “Some or all of this information is processed by the workstation computer 64 to derive a set of variables,” where “The navigation control algorithm determines a set of actuation control variables {u} which when applied drive the device towards the user-specified target criteria, given all the available inputs.” (see ¶ [0031])

The Application discloses a “workstation computer 64 that is connected to a graphical user interface 67” where the “interface includes at least two computer programs that run on the processor.” (see ¶ [0021], [0029]) As noted above, information is processed by workstation computer 64 to derive a set of variables characterizing device configuration, where a “navigation control algorithm determines a set of actuation control variables {u} which when applied drive the device towards the user-specified target.” (¶ [0031])

Independent Claim 38

A medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device;

a memory device provided on the flexible medical device that includes information on the physical and geometric properties including one or more cross-sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device;

a control system for controlling the position and/or orientation of the distal end of the elongate medical device, where the one or more cross-sectional areas of the device, and the elastic property of the device are used in navigational control algorithms for guiding the device;

an interface for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device; the interface sending actuation instructions to the control system dependent in part upon the medical device's physical and geometric property information, including the one or more cross-sectional areas of the device, and the elastic property of the device obtained from the memory device, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device.

With regard to independent claim 38, the present application states in ¶ [0022] that "the medical device 51 generally comprises a flexible and usually hollow shaft 97," and that "A device identification pod 121 incorporating stored electronic identification information is affixed to the device."

The "device identification stored in pod 121 discloses a set {p} of physical and geometrical properties...[which] include one or more of several quantities such as length of device segments, elastic properties of device segments, stiffness, device cross sectional details." (see ¶ [0030])

The Application discloses "navigation control system could operate conventional pull wires built into the elongate medical device, or it could hydraulically operate chambers built into the medical device, or operate magnetostrictive or electrostrictive elements built into the elongate medical device." The navigational control system may also be a "magnet system that creates a magnetic field that can be used to steer the device 51." (see ¶ [0020])

With regard to the set of physical and geometrical properties, the Application states that "Some or all of this information is processed by the workstation computer 64 to derive a set of variables," where "The navigation control algorithm determines a set of actuation control variables {u} which when applied drive the device towards the user-specified target criteria, given all the available inputs." (see ¶ [0031])

The Application discloses a "workstation computer 64 that is connected to a graphical user interface 67" (see ¶ [0021]) The Application discloses "user inputs are accepted through any of the user input devices that may be the mouse 69, keyboard 70, pen tablet 71, device advancer 72 or joystick 73...[which] inputs generally dictate a choice of target location." (see ¶ [0031]) As noted above, information is processed by workstation computer 64 to derive a set of variables characterizing the device configuration, where a "navigation control algorithm determines a set of actuation control variables {u} which when applied drive the device towards the user-specified target." (see ¶ [0031])

Independent Claim 52

A medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device including at least one magnet;

a memory device provided on the flexible medical device that includes information on the physical and geometric properties of the elongate medical device that are relevant to navigational control of the device;

a control system for controlling the position and/or orientation of the distal end of the elongate medical device; wherein the control system is a magnetic navigation system for controlling the elongate medical device that further includes at least one magnet, and said information includes physical properties of the elongate medical device including at least a magnet dimension or a magnet type; and

an interface for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device; the interface sending actuation instructions to the control system dependent in part upon the medical device's physical and geometric property information including the magnet dimension or magnet type obtained from the memory device, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device.

With regard to independent claim 52, the present application states in ¶ [0022] that “the medical device 51 generally comprises a flexible and usually hollow shaft 97, a magnetically responsive element 101 that imparts device actuation in the distal portion” and “A device identification pod 121 incorporating stored electronic identification information is affixed to the device.”

The Application discloses “a navigational control system 57” which is a “magnet system that creates a magnetic field that can be used to steer the device 51...[where] a magnetically responsive element on the distal end of the medical device responds to the external magnetic field to change the direction of the distal end.” (see ¶ [0020])

The "device identification stored in pod 121 discloses a set {p} of physical and geometrical properties...[which] include one or more of several quantities such as length of device segments, elastic properties of device segments, stiffness, device cross sectional details, magnet dimensions, magnet type and other magnet characteristics, the number of magnets and their spacing." (see ¶ [0030])

The Application discloses a "workstation computer 64 that is connected to a graphical user interface 67" (see ¶ [0021]) The Application discloses "user inputs are accepted through any of the user input devices that may be the mouse 69, keyboard 70, pen tablet 71, device advancer 72 or joystick 73...[which] inputs generally dictate a choice of target location." (see ¶ [0031])

With regard to the set of physical and geometrical properties, the Application states that "Some or all of this information is processed by the workstation computer 64 to derive a set of variables," where "The navigation control algorithm determines a set of actuation control variables {u} which when applied drive the device towards the user-specified target criteria, given all the available inputs." (see ¶ [0031]).

GROUND'S FOR REJECTION TO BE REVIEWED ON APPEAL – UNDER 37 C.F.R. § 41.37(c)(1)(vi)

Appellants present the following issues for review:

1. Is the invention set forth in Claims 1-6, 8-9, 11-17, 38-40 and 52 non-obvious under 35 U.S.C. § 103(a), over *Stereotaxis* (WO 00/07641) in view of *Osadchy* (U.S. Pat. No. 6,266,551).
2. Is the invention set forth in Claim 10 non-obvious under 35 U.S.C. § 103(a), over *Stereotaxis* (WO 00/07641) in view of *Osadchy* (U.S. Pat. No. 6,266,551) in further view of *Burnside* (6,237,604).

ARGUMENT – UNDER 37 C.F.R. § 41.37(c)(1)(vii)

1. 1st GROUND OF REJECTION ON APPEAL

Pursuant to 37 C.F.R. § 41.37(c)(1)(vii), the following provides the contentions of appellants with respect to the 1st ground of rejection above presented for review in accordance with 37 C.F.R. § 41.37(c)(1)(vi).

Independent Claim 1

Claim 1 is not obvious over *Stereotaxis* in view of *Osadchy* for the following reasons:

I. There is no apparent reason why an artisan considering *Osadchy's* teaching of a calibration offset would combine such teaching with *Stereotaxis* in a manner that would result in the fashion claimed, of a device that stores the number of magnetically responsive elements and spacing between for use in determining navigation variables

II. The combination of references would not have been productive of the claimed device

I. The Claimed Invention Is Not Obvious Over *Stereotaxis* And *Osadchy*, Since There Is No Apparent Reason Why An Artisan Considering *Osadchy's* Teaching Of A Calibration Offset Would Combine Such Teaching With *Stereotaxis* In A Manner That Would Result In The Fashion Claimed Of A Device With Information On The Number Of Magnetic Elements For Use In Determining Navigation Variables

The Final Office Action states on page 4 that *Osadchy* discloses a device having electronic information on physical properties of the device that includes the number of magnetically responsive elements 60, 62, 64 and spacing there between (dy and dz), where the number of magnetically responsive elements and spacing are used to determine calibration correction data to enable proper determination of the tip location.

However, *Osadchy* merely discloses a distance L from a coil 62 to a tip 26, which is used for calibration, where “due to deviations in the process of manufacturing catheter 20, the distance L typically varies from one catheter to another.” (*Osadchy*, c. 11, ll. 26-28; c. 12, ll. 3-6). *Osadchy* teaches a position signal generating device 28, where “magnetic fields cause coils 60, 62 and 64 in device 28 to generate signals” and a computer uses “the position and orientation signals generated by device 28, in order to determine the actual, correct position of tip 26”. (*Osadchy*, c. 10, ll. 55; c. 15, ll. 6-7). *Osadchy*’s distance L is merely used as an offset to calibrate the determination of the actual position of the tip of a particular catheter. (*Osadchy*, c. 15, ll. 17-21).

Thus, even if one skilled in the art had combined the *Stereotaxis* system with *Osadchy*’s teaching of a calibration offset for determining distance between a sensing coil and the actual tip location, it would not have resulted in a system that provides actuation instructions that take into account information on the number of magnetically responsive elements and spacing therebetween.

As the Supreme Court said, there must be an apparent reason to combine known elements in the references in a manner that would result in the fashion claimed by the patent application. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). The Examiner has not articulated a sufficient reason why one skilled in the art would have modified *Osadchy*’s teaching of a calibration offset distance to arrive at the presently claimed invention of information including the number of magnetically responsive elements and spacing therebetween that are used in determining navigational control variables for orienting/guiding the distal end of the medical device. Thus, the Appellant submits that claim 1 is not obvious in view of *Osadchy*’s teachings.

II. The Claimed Invention Is Not Obvious In View Of *Stereotaxis* And *Osadchy*, Since An Artisan Combining *Stereotaxis* And *Osadchy* Would Merely Have Arrived At The Predictable Result Of *Osadchy*'s Catheter With A Calibration Offset, And Would Not Have Been Productive Of Appellant's Device With Information On The Number Of Magnetic Elements For Use In Determining Navigation Variables

A person of ordinary skill in the art considering *Osadchy*'s teachings might have recognized that the *Stereotaxis* system could be improved by including *Osadchy*'s stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip. Thus, a skilled artisan would have been motivated to leave the *Stereotaxis* system as is, and to merely include *Osadchy*'s teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the tip of the catheter.

The Federal Circuit has stated that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the Appellant, or the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellant. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Here, one skilled in the art considering *Osadchy* would not have thought of including the number of magnetic elements that could be used in determining navigational control variables for orienting the medical device, and would simply have followed the line of development flowing from *Osadchy* of including a calibration offset, and would not have been productive of the Appellant's invention.

Osadchy's teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip is not the same as Appellant's

device that stores the number of magnetically responsive elements and spacing therebetween, which are used in determining navigational control variables for orienting/guiding the distal end of the medical device.

The Supreme Court has stated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). Here, only the combination of *Stereotaxis* with *Osadchy's* known calibration distance between a sensing coil and tip would be obvious, since it does no more than yield the predictable result of merely a medical device having a stored value representative of the distance between a sensing coil and a tip. There is no articulated reason why one skilled in the art would have combined *Osadchy's* teachings of an offset in a manner that would have predictably resulted in including a number of magnetically responsive elements and the spacing therebetween, for use in determining navigational control variables for orienting/guiding the distal end of the medical device. As such, the Appellant submits that it would not have been obvious to a person of ordinary skill to combine *Osadchy's* teachings according to known methods in a manner that would have predictably resulted in a medical device as in claim 1 having stored information including a number of magnetically responsive elements.

Independent Claim 38

Claim 38 is not obvious over the above cited references for the following reasons:

I. There is no apparent reason why an artisan considering *Osadchy's* teaching of a calibration offset would combine such teaching with *Stereotaxis* in a manner that would result in the fashion claimed, of a device that stores the cross-sectional area and elastic properties of the device for use in determining navigation variables

II. The combination of references would not have been productive of the claimed device

I. The Claimed Invention Is Not Obvious Over *Stereotaxis* And *Osadchy*, Since There Is No Apparent Reason Why An Artisan Considering *Osadchy's* Teaching Of A Calibration Offset Would Combine Such Teaching With *Stereotaxis* In A Manner That Would Result In The Fashion Claimed Of A Device With Information On Device Elasticity/Cross-sectional Area For Use In Determining Navigation Variables

The Final Office Action states on page 9 that *Osadchy* discloses a device having electronic information on physical properties of the device that includes geometric properties including the position of the tip 26 relative to coils 60, 62, 64, where the information is used to determine calibration correction data to enable proper determination of the tip location.

However, *Osadchy* merely discloses a distance L from a coil 62 to a tip 26, which is used for calibration, where "due to deviations in the process of manufacturing catheter 20, the distance L typically varies from one catheter to another." (*Osadchy*, c 11, ll. 26-28; c. 12, ll. 3-6). *Osadchy* teaches a position signal generating device 28,

where "magnetic fields cause coils 60, 62 and 64 in device 28 to generate signals" and a computer uses "the position and orientation signals generated by device 28, in order to determine the actual, correct position of tip 26". (Osadchy, c. 10, ll. 55; c. 15, ll. 6-7). *Osadchy's* distance L is merely used as an offset to calibrate the determination of the actual position of the tip of a particular catheter. (Osadchy, c. 15, ll. 17-21).

Thus, even if one skilled in the art had combined the *Stereotaxis* system with *Osadchy's* teaching of a calibration offset for determining distance between a sensing coil and the actual tip location, it would not have resulted in a system that provides actuation instructions to a navigation device that take into account information including the cross-sectional area and elastic properties of the device. As the Supreme Court stated, there must be an apparent reason to combine the known elements in the references in a manner that would result in the fashion claimed by the patent application. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). The Examiner has not articulated a sufficient reason why one skilled in the art would have modified *Osadchy's* teaching of a calibration offset distance to arrive at the presently claimed invention of information including the cross-sectional area and elastic properties of the device that could be used in determining navigational control variables for orienting/guiding the distal end of the medical device. Thus, the Appellant submits that claim 38 is not obvious in view of *Osadchy's* teachings.

II. The Claimed Invention Is Not Obvious In View Of Stereotaxis And Osadchy, Since An Artisan Combining Stereotaxis And Osadchy Would Merely Have Arrived At The Predictable Result Of Osadchy's Catheter With A Calibration Offset, And Would Not Have Been Productive Of Appellant's Device With Information On Cross-sectional Area Of The Device For Use In Determining Navigation Variables

A person of ordinary skill in the art considering *Osadchy's* teachings may have recognized that the *Stereotaxis* system could be improved by including a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip as in *Osadchy*. Thus, a skilled artisan would have been motivated to leave the *Stereotaxis* system as is, and to merely include *Osadchy's* teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the tip of the catheter.

The Federal Circuit has also stated that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the Appellant, or the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellant. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Here, one skilled in the art considering *Osadchy* would not have thought of including the cross-sectional area and elastic properties of the device that could be used in determining navigational control variables for orienting the medical device, and would simply have followed the line of development flowing from *Osadchy* of including a calibration offset, and would not have been productive of the Appellant's invention.

Osadchy's teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip is not the same as Appellant's device that stores the cross-sectional area and elastic properties of the device, which

are used in determining navigational control variables for orienting/guiding the distal end of the medical device. The Supreme Court has stated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). Here, only the combination of *Stereotaxis* with *Osadchy's* known calibration representing the distance between a sensing coil and tip would be obvious, since it does no more than yield the predictable result of merely a medical device having a stored value representative of the distance between a sensing coil and a tip. There is no articulated reason why one skilled in the art would have combined *Osadchy's* teachings of an offset in a manner that would have predictably resulted in including the cross-sectional area and elastic properties of the device, for use in determining navigational control variables for orienting/guiding the distal end of the medical device. As such, the Appellant submits that it would not have been obvious to a person of ordinary skill to combine *Osadchy's* teachings according to known methods in a manner that would have predictably resulted in a medical device as in claim 38 having stored information including a cross-sectional area and elastic properties of the device.

Independent Claim 52

Claim 52 is not obvious over the above cited references for the following reasons:

I. There is no apparent reason why an artisan considering *Osadchy's* teaching of a calibration offset would combine such teaching with *Stereotaxis* in a manner that would result in the fashion claimed, of a device that stores the number of magnetically responsive elements and spacing between for use in determining navigation variables

II. The combination of references would not have been productive of the claimed device

I. The Claimed Invention Is Not Obvious Over *Stereotaxis* And *Osadchy*, Since There Is No Apparent Reason Why An Artisan Considering *Osadchy's* Teaching Of A Calibration Offset Would Combine Such Teaching With *Stereotaxis* In A Manner That Would Result In The Fashion Claimed Of A Device With Information On The Number Of Magnetic Elements For Use In Determining Navigation Variables

The Final Office Action states on page 4 that *Osadchy* discloses a device having electronic information on physical properties of the device that includes the number of magnetically responsive elements 60, 62, 64 and spacing there between (dy and dz), where the number of magnetically responsive elements and spacing are used to determine calibration correction data to enable proper determination of the tip location.

However, *Osadchy* merely discloses a distance L from a coil 62 to a tip 26, which is used for calibration, where "due to deviations in the process of manufacturing catheter 20, the distance L typically varies from one catheter to another." (*Osadchy*, c

11, ll. 26-28; c. 12, ll. 3-6). *Osadchy* teaches a position signal generating device 28, where "magnetic fields cause coils 60, 62 and 64 in device 28 to generate signals" and a computer uses "the position and orientation signals generated by device 28, in order to determine the actual, correct position of tip 26". (*Osadchy*, c. 10, ll. 55; c. 15, ll. 6-7). *Osadchy's* distance L is merely used as an offset to calibrate the determination of the actual position of the tip of a particular catheter. (*Osadchy*, c. 15, ll. 17-21).

Thus, even if one skilled in the art had combined the *Stereotaxis* system with *Osadchy's* teaching of a calibration offset for determining distance between a sensing coil and the actual tip location, it would not have resulted in a system that provides actuation instructions to a navigation device that take into account information on the number of magnetically responsive elements and spacing therebetween. As the Supreme Court stated, there must be an apparent reason to combine the known elements in the references in a manner that would result in the fashion claimed by the patent application. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). The Examiner has not articulated a sufficient reason why one skilled in the art would have modified *Osadchy's* teaching of a calibration offset distance to arrive at the presently claimed invention of information including the number of magnetically responsive elements and spacing therebetween, which are used in determining navigational control variables for orienting/guiding the distal end of the medical device. Thus, the Appellant submits that claim 52 is not obvious in view of *Osadchy's* teachings.

II. The Claimed Invention Is Not Obvious In View Of *Stereotaxis* And *Osadchy*, Since An Artisan Combining *Stereotaxis* And *Osadchy* Would Merely Have Arrived At The Predictable Result Of *Osadchy*'s Catheter With A Calibration Offset, And Would Not Have Been Productive Of Appellant's Device With Information On The Number Of Magnetic Elements For Use In Determining Navigation Variables

A person of ordinary skill in the art considering *Osadchy*'s teachings may have recognized that the *Stereotaxis* system could be improved by including a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip as in *Osadchy*. Thus, a skilled artisan would have been motivated to leave the *Stereotaxis* system as is, and to merely include *Osadchy*'s teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the tip of the catheter.

The Federal Circuit has also stated that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the Appellant, or the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellant. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Here, one skilled in the art considering *Osadchy* would not have thought of including the number of magnetic elements that could be used in determining navigational control variables for orienting the medical device, and would simply have followed the line of development flowing from *Osadchy* of including a calibration offset, and would not have been productive of the Appellant's invention.

Osadchy's teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip is not the same as Appellant's device that stores the number of magnetically responsive elements and spacing

therebetween, which are used in determining navigational control variables for orienting/guiding the distal end of the medical device. The Supreme Court has stated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). Here, only the combination of *Stereotaxis* with *Osadchy's* known calibration representing the distance between a sensing coil and would be obvious, since it does no more than yield the predictable result of merely a medical device having a stored value representative of the distance between a sensing coil and a tip. There is no articulated reason why one skilled in the art would have combined *Osadchy's* teachings of an offset in a manner that would have predictably resulted in including a number of magnetically responsive elements and the spacing therebetween, for use in determining navigational control variables for orienting/guiding the distal end of the medical device. As such, the Appellant submits that it would not have been obvious to a person of ordinary skill to combine *Osadchy's* teachings according to known methods in a manner that would have predictably resulted in a medical device as in claim 52 having stored information including a number of magnetic elements.

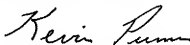
Claims 2-6, 8-9, 10-17 and 39-40

With regard to claims 2-6, 8-9, 10-17 and 39-40, these claims ultimately depend from claim 1, 38 or 51, which Appellants believe to be allowable in view of the above remarks. As such, the Appellants submit that claims 2-6, 8-9, 10-17 and 39-40 are also allowable for at least these reasons.

CONCLUSION

Appellants respectfully submit that the Examiner has not shown that claims 1-6, 8-9, 11-17, 38-40 and 52 non-obvious under 35 U.S.C. § 103(a), over *Stereotaxis* (WO 00/07641) in view of *Osadchy* (U.S. Pat. No. 6,266,551). Accordingly, reversal of the rejections of Claims 1-6, 8-9, 10-17, 38-40 and 52 are respectfully requested.

Respectfully submitted,



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Date: September 22, 2008

CLAIMS APPENDIX
UNDER 37 C.F.R. § 41.37(c)(1)(viii)

1. (Previously Presented) A medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body, the system comprising:

an elongate flexible medical device having on its distal end portion one or more magnetically responsive elements that respond to an externally applied magnetic field to change the direction of the distal end of the medical device, and an electronic identification device on the elongate medical device that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, and identification information that provides for elongate flexible medical device identification;

a navigation device configured to create a magnetic field used to steer the elongate flexible medical device, and to determine, as a function of the physical and geometric properties, actuation control variables for an applied actuation consisting essentially of an external magnetic field, where the navigation device determines and applies an appropriate magnetic field direction for actuating the distal end of an elongate flexible medical device and thereby changing its orientation;

an electronic interface for selectively operating the navigation device for selectively controlling the orientation of the distal end of the elongate flexible medical device, the electronic interface comprising a processor and at least one software program that enables navigation control only in the presence of the electronic identification device, wherein the interface provides actuation instructions to the navigation device for controlling the distal end of the device, which instructions take into account the physical and geometric properties of the elongate medical device, including the number of magnetically responsive elements and spacing therebetween, that were obtained from the electronic identification device.

2. (Original) The medical navigation system according to claim 1 wherein the electronic identification device includes a memory, and wherein the interface includes a reader for reading the memory.

3. (Original) The medical navigation system according to claim 1 wherein the electronic identification device includes a memory unit and a processing unit that communicates with the interface for transferring information.

4. (Original) The medical navigation system according to claim 2 wherein the memory contains unique identifying information about the type of device, and wherein the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate.

5. (Original) The medical navigation system according to claim 3 wherein the memory contains unique identifying information about the type of device, and wherein the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate.

6. (Original) The medical navigation system according to claim 1 wherein the electronic identification device is a circuit that is connected to the interface.

7. (Cancelled)

8. (Original) The medical navigation system according to claim 2 wherein the memory contains unique identifying information about the device, and wherein the interface includes a database of the unique identifying information for devices with which the interface is intended to operate.

9. (Original) The medical navigation system according to claim 3 wherein the memory contains unique identifying information about the device, and wherein the interface includes a database of the unique identifying information for devices with which the interface is intended to operate.

10. (Original) The medical navigation system according to claim 1 wherein the electronic identification device is a RF circuit that transmits a signal to the interface.

11. (Original) The medical navigation system according to claim 1 wherein the interface includes a plurality of programs, each adapted for use with a different type of elongate flexible medical device, each program operating only when an electronic identification device for the particular type of elongate flexible medical device is present.

12. (Original) The medical navigation system according to claim 1 wherein the electronic identification device includes an integrated circuit.

13. (Original) The medical navigation system according to claim 1 wherein the interface operates on the electronic identification device to prevent reuse of the elongate flexible medical device.

14. (Original) The medical navigation system according to claim 1 wherein the interface tracks elapsed time of use of the identified elongate flexible medical device and invalidates use of the identified elongate flexible medical device when the elapsed time exceeds a pre-defined limit.

15. (Original) The electronic identification device according to claim 3 wherein the processing unit operates on the memory unit to prevent reuse of the elongate flexible medical device.

16. (Original) The medical navigation system according to claim 1 wherein the electronic identification device includes memory, and wherein the interface adds to or deletes information stored on the memory to prevent reuse of the device.

17. (Original) The medical navigation system according to Claim 1 wherein the at least one software program controls navigation by employing a computational model of flexible device physics.

18. – 37. (Cancelled)

38. (Previously Presented) A medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device;

a memory device provided on the flexible medical device that includes information on the physical and geometric properties including one or more cross-sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device;

a control system for controlling the position and/or orientation of the distal end of the elongate medical device, where the one or more cross-sectional areas of the device,

and the elastic property of the device are used in navigational control algorithms for guiding the device;

an interface for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device; the interface sending actuation instructions to the control system dependent in part upon the medical device's physical and geometric property information, including the one or more cross-sectional areas of the device, and the elastic property of the device obtained from the memory device, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device.

39. (Original) The medical navigation system according to claim 38 wherein the interface incorporates a software program that controls navigation by employing a computational model of flexible device physics.

40. (Original) The system according to claim 38 wherein the memory device includes storing unique device identification information for the elongate flexible medical device, and wherein the interface includes a database of unique device identification information and corresponding device properties, and wherein the instructions sent to the control system take into account the device properties determined from the database.

41. – 51. (Cancelled)

52. (Currently Amended) A medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device including at least one magnet;

a memory device provided on the flexible medical device that includes information on the physical and geometric properties of the elongate medical device that are relevant to navigational control of the device;

a control system for controlling the position and/or orientation of the distal end of the elongate medical device; wherein the control system is a magnetic navigation system for controlling the elongate medical device that further includes at least one

magnet, and said information includes physical properties of the elongate medical device including at least a magnet dimension or a magnet type; and

an interface for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device; the interface sending actuation instructions to the control system dependent in part upon the medical device's physical and geometric property information including the magnet dimension or magnet type obtained from the memory device, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device.

53. (Cancelled)

EVIDENCE APPENDIX UNDER 37 C.F.R. § 41.37(c)(1)(IX)

- A copy of the Office Action mailed March 27, 2008 placing the present application under final rejection is provided.

RELATED PROCEEDINGS APPENDIX - UNDER 37 C.F.R. § 41.37(c)(1)(x)

NONE.